



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,878	11/14/2006	Herwig Ponstingl	2000321.120 US1	3941

28089 7590 11/15/2007
WILMERHALE/NEW YORK
399 PARK AVENUE
NEW YORK, NY 10022

EXAMINER

HAMA, JOANNE

ART UNIT	PAPER NUMBER
----------	--------------

1632

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

11/15/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

michael.mathewson@wilmerhale.com
teresa.carvalho@wilmerhale.com
sharon.matthews@wilmerhale.com

Office Action Summary

Application No.

10/551,878

Applicant(s)

PONSTINGL ET AL.

Examiner

Joanne Hama, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

This Application, filed November 14, 2006, is a 371 of PCT/EP04/03538, filed April 2, 2004, and claims priority to Application 03007680.6, filed April 3, 2003, in the European Patent Office.

Applicant filed an amendment to the claims, September 30, 2005. Claims 1-5,7-15,17 are amended. Claims 16, 18-20 are cancelled. Claims 21-39 are new.

Claims 1-15, 17, 21-39 are pending.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-5, 12, 13, 15, 17, 27, 29, 34, 35 drawn to an isolated nucleic acid encoding a human dystrophin-related polypeptide Drop1, a recombinant vector comprising the nucleic acid encoding human Drop1, a cell comprising the recombinant vector comprising the nucleic acid encoding human Drop1, a pharmaceutical composition comprising a nucleic acid encoding Drop1, a method for treating cancer comprising administering to a subject an effective amount of nucleic acid encoding Drop 1.

Group 2, claim(s) 6, 7, drawn to a non-human transgenic animal characterized by the loss of Drop1 function.

Group 3, claim(s) 8-10, 14, 15, 17, 21, 22, 25, 26, 36, 37 drawn to a Drop1 polypeptide, a method of making Drop1 polypeptide, and a method for identifying an activator of Drop1.

Group 4, claim(s) 11, 15, 17, 23, 24, 30, 38, 39, drawn to an antibody that binds to Drop1, a method of treating cancer comprising administering Drop1 antibody.

Group 5, claim(s) 28, drawn to a method of treating cancer comprising administering Drop1 polypeptide.

Group 6, claim(s) 31, drawn to a method for treating cancer comprising administering an activator or agonist of Drop1.

Group 7, claim(s) 32, 33, drawn to a method of diagnosing and/or characterizing a tumor or predisposition to a tumor comprising determining Drop1 nucleic acid expression.

The inventions listed as Groups 1-7 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: unity of invention between different categories of inventions will only be found to exist if the specific combinations are present. These combinations include:

- 1) a product and special process of manufacture of said product,
- 2) a product and a process of use of said product,
- 3) a product, a special process of manufacture of said product, and a process of use of said product,
- 4) a process and an apparatus specially designed to carry out said process,
- 5) a product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said product, and methods of making multiple products as claimed in the instant application, see MPEP § 1850.

In addition to this, the special technical feature of the Application is Drop1 protein. Claim 1 includes a polypeptide exhibiting a biological property of Drop1. According to the specification, enaptin has high homology to Drop1 (specification, page

Art Unit: 1632

3, 2nd parag.). Enaptin, submitted by Abraham et al. Genbank [online], 2002 [retrieved on line 2007-10-30]. Retrieved from the Internet:

<http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nuccore&id=22597197>, pages 1-12

(Genbank accession number AF535142), was known at the time of filing, and thus, the Invention lacks unity.

The claims are further restricted.

Claim 1 of Group 1 is drawn to multiply named SEQ ID NOs and one must be elected. Each of the sequences is distinct from the other as each encodes a distinct peptide.

Claim 1 of Group 1 is drawn to sense and antisense (see claim 1d) nucleic acids and either sense or antisense must be elected. Antisense is distinct from sense as it has a different structure and function than that of sense nucleic acids.

Claim 8 of Group 3 is drawn to a polypeptide encoded by a SEQ ID NO., as listed in claim 1, and one SEQ ID NO. must be elected. Each of the sequences is distinct from each other because they encode different peptides, each of which has distinct biological activities.

Claim 11 of Group 4 is drawn to an antibody made from the peptide of claim 8, which is encoded by a SEQ ID NO., as listed in claim 1, and one SEQ ID NO. must be elected. Each of the antibodies is distinct from the other because they detect different peptides, each of which has distinct biological activities.

Claim 28 of Group 5 is drawn to the use of distinctly named Drop1 polypeptides encoded by the SEQ ID NOs. listed in claim 1, and one SEQ ID NO. must be elected.

Art Unit: 1632

Each of the SEQ ID NOs. encode a peptide, each of which has a distinct biological activity.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

Application/Control Number: 10/551,878


Page 7

Art Unit: 1632

also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Joanne Hama

Art Unit 1632

Handwritten signature of Joanne Hama in black ink.